

WHAT IS CLAIMED IS:

1. A combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia, comprising:
 - a catheter body having a proximal end and a distal end;
 - an ionizing radiation source coupleable to the catheter body for applying a radiation dose to a body lumen; and
 - means coupleable to the catheter body or the radiation source for releasing a radiosensitizer to the body lumen.
2. A delivery catheter as in claim 1, wherein the ionizing radiation source is an x-ray tube.
3. A delivery catheter as in claim 1, wherein the ionizing radiation source is a radioisotope.
4. A delivery catheter as in claim 1, wherein the ionizing radiation source is a receptacle in the catheter body for receiving radioisotopic materials.
5. A delivery catheter as in claim 1, wherein the means comprises a source of at least one radiosensitizer selected from the group consisting of taxol, misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and cyclooxygenase-2 inhibitor.
6. A delivery catheter as in claim 1, wherein the means comprises a source of taxol incorporated in a solution with polyoxyethylated castor oil and dehydrated alcohol.
7. A delivery catheter as in claim 1, wherein the radiosensitizer is attached or encapsulated in a lipid or surfactant carrier.
8. A delivery catheter as in claim 1, wherein the means for releasing the radiosensitizer comprises a microporous balloon on the catheter body.
9. A delivery catheter as in claim 8, wherein the microporous balloon contains the radiosensitizer and the radiosensitizer is released from the microporous balloon by elution from pores.

1 10. A delivery catheter as in claim 9, wherein the microporous balloon is
2 inflatable with the radiosensitizer.

1 11. A delivery catheter as in claim 1, wherein the means for releasing the
2 radiosensitizer comprises a matrix formed over at least a portion of a balloon on the catheter
3 body, wherein the radiosensitizer is in or beneath the matrix.

1 12. A delivery catheter as in claim 11, wherein the matrix comprises a rate
2 controlling material, wherein the rate controlling material controls the rate at which the
3 radiosensitizer is released from or through the matrix.

1 13. A delivery catheter as in claim 12, wherein the radiosensitizer is
2 released from the matrix by diffusion through the matrix.

1 14. A delivery catheter as in claim 12, wherein the radiosensitizer is
2 released from the matrix by degradation of the matrix.

1 15. A delivery catheter as in claim 12, wherein the rate controlling material
2 is porous and the radiosensitizer is released from the material by elution from pores.

1 16. A delivery catheter as in claim 11, wherein the radiosensitizer is
2 disposed on the balloon.

1 17. A delivery catheter as in claim 8 or 11, wherein the ionizing radiation
2 source is positionable within the balloon.

1 18. A delivery catheter as in claim 1, wherein the ionizing radiation source
2 is a radioisotopic balloon and the means for releasing the radiosensitizer comprises a matrix
3 formed over at least a portion of the radioisotopic balloon, wherein the radiosensitizer is in or
4 beneath the matrix.

1 19. A delivery catheter as in claim 8, 11, or 18, further comprising
2 perfusion threading on an outer surface of the balloon.

1 20. A delivery catheter as in claim 19, wherein the threading has a spiral,
2 helical, or angled pattern.

1 21. A delivery catheter as in claim 8, 11, or 18, wherein the catheter body
2 has a perfusion lumen.

1 22. A combined radiation and radiosensitizer delivery catheter for
2 inhibiting hyperplasia, comprising:
3 a catheter body having a proximal end, a distal end, and an infusion lumen for
4 releasing a radiosensitizer;
5 a pair of axially spaced apart balloons on the catheter body; and
6 an ionizing radiation source coupleable to the catheter body for applying a
7 radiation dose between the axially spaced apart balloons.

1 23. A delivery catheter as in claim 22, further comprising a source for
2 releasing at least one radiosensitizer selected from the group consisting of taxol,
3 misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and
4 cyclooxygenase-2 inhibitor.

1 24. A method for inhibiting hyperplasia in a body lumen, said method
2 comprising:
3 releasing a radiosensitizer at a target region within the body lumen; and
4 directing ionizing radiation at the target region, wherein the radiosensitizer
5 and radiation combine to inhibit hyperplasia.

1 25. A method as in claim 24, further comprising inflating a balloon at the
2 target region, where the radiosensitizer is released from the balloon.

1 26. A method as in claim 25, wherein the balloon is inflated with the
2 radiosensitizer and the radiosensitizer is released from an interior of the balloon through
3 pores.

1 27. A method as in claim 25, wherein the radiosensitizer is released from a
2 surface of the balloon.

1 28. A method as in claim 27, wherein the radiosensitizer is released
2 through a rate controlling matrix.

1 29. A method as in claim 24, further comprising isolating the target region,
2 wherein the radiosensitizer is released into the isolated region.

1 30. A method as in claim 29, wherein isolating comprises inflating a pair
2 of axially spaced apart balloons.

1 31. A method as in claim 29, wherein isolating comprises expanding a pair
2 of axially spaced apart mechanical barriers.

1 32. A method as in claim 25, wherein the directing comprises positioning
2 an ionizing radiation source within the balloon.

1 33. A method as in claim 29, wherein the directing comprises positioning
2 an ionizing radiation source within the isolated target region.

1 34. A method as in claim 32 or 33, wherein the ionizing radiation source is
2 an x-ray tube and positioning comprises energizing the x-ray tube and translating the x-ray
3 tube to traverse the target region.

1 35. A method as in claim 32 or 33, wherein the ionizing radiation source is
2 a radioisotope.

1 36. A method as in claim 32 or 33, wherein the ionizing radiation source is
2 a receptacle in the catheter body and positioning comprises introducing a radioisotope into
3 the receptacle.

1 37. A method as in claim 24, wherein the body lumen is a blood vessel and
2 the target region is a region at risk of hyperplasia.

1 38. A method as in claim 24, wherein the directing comprises applying a
2 total radiation dose in a range from about 4 Gy to 24 Gy.

1 39. A method as in claim 24, wherein the releasing a radiosensitizer and
2 directing an ionizing radiation dose are carried out simultaneously.

1 40. A method as in claim 24, wherein the releasing a radiosensitizer and
2 directing an ionizing radiation dose are carried out sequentially.

- 1 41. A kit comprising:
- 2 a catheter capable of applying a radiation dose and releasing a radiosensitizer
- 3 in a body lumen; and
- 4 instructions to use the catheter according to any one of claims 24-40.
- 1 42. A kit as in claim 41, further comprising a source of radiosensitizer.